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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,429	01/04/2002	Jeffrey H. Burbank	266/153	7194

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PROSKAUER ROSE LLP
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EXAMINER

FRANK, RODNEY T

ART UNIT PAPER NUMBER

2856

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,429	BURBANK, JEFFREY H.	
	Examiner	Art Unit	
	Rodney T. Frank	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 5, 12, 15, 17, 18, 20, 25, 38, 39, 47, 60, 61, 65-79 and 81-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 3, 5, 12, 15, 17, 18, 20, 25, 38, 39, 47, 60, 61, 65-79, and 81-83 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 3, 76, and 79, drawn to a method of detecting leaks in an extracorporeal blood circuit wherein said second step of detecting includes applying a positive gauge pressure to the circuit at a first time and a negative pressure to the circuit at a second time, classified in class 340, subclass 605.
 - II. Claims 5 and 69, drawn to a method of detecting leaks in an extracorporeal blood circuit wherein said second step of detecting includes periodically reversing flow in said blood circuit, classified in class 340, subclass 605.
 - III. Claims 12, 15, 47, 66-68, and 78, drawn to a leak detection system in an extracorporeal blood circuit wherein a mechanism at least periodically creates a negative pressure in all portions of patient side of the circuit wherein said mechanism includes a device adapted to reverse flow direction in said circuit, classified in class 73, subclass 40.
 - IV. Claims 17, 18, 20, 60, 61, 70-73, 74, and 81-83, drawn to a device to detect leaks in a blood circuit comprising first and second leak detectors a mechanism to generate a negative pressure, and an alarm to signal a detection by said first and second detectors, classified in class 73, subclass 40.
 - V. Claim 25, drawn to a method of detecting leaks in an extracorporeal blood circuit wherein said second step of generating includes periodically reversing flow in said blood circuit, classified in class 340, subclass 605.

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- VI. Claims 38 and 39, drawn to a method of detecting leaks in a blood circuit wherein leakage is detected in respective portions of said blood circuit said respective portions are non-overlapping, classified in class 73, subclass 40.
- VII. Claim 65, drawn to detecting blood in a normally dry first portion of a blood circuit, detecting air in a second portion, wherein said step of detecting air includes periodically reversing flow in said blood circuit, classified in class 73, subclass 40.
- VIII. Claim 75, drawn to a method of detecting leaks in a blood circuit wherein a pumping of blood is halted in either or both blood circuit portions responsive to either or both of said steps of detecting, classified in class 73, subclass 40.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II, III, IV, V, VI, and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Group I is the only group that requires a positive pressure to be applied in order for it to work.

3. Inventions II and I, III, IV, V, VI, and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of

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the subcombination as claimed because Group II is the only group that requires the second detecting step to reverse flow in the blood circuit.

4. Inventions III and I, II, IV, V, VI, and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Group III requires a mechanism to at least periodically generate a negative pressure and said mechanism is adapted to reverse flow direction in said blood circuit.

5. Inventions IV and I, II, III, V, VI, and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because group IV does not require a reverse fluid flow in order to operate its method.

6. Inventions V and I, II, III, IV, VI, and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Group V requires generating a response including an

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alarm wherein said generating step includes reversing flow direction of fluid with no need of pressure, which is not required in any other group.

7. Inventions VI and I, II, III, IV, V, and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Group VI requires sensing various physical effects of various portions of a blood circuit wherein the various portions are non-overlapping portions.

8. Inventions VII and I, II, III, I, VI, and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Group Vii discloses a method for detecting leaks that does not require applying a negative pressure.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II, III, IV, V, VI, and VII, restriction for examination purposes as indicated is proper.

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11. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Groups I, III, IV, V, VI, and VII, restriction for examination purposes as indicated is proper.

12. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Groups I, II, IV, V, VI, and VII, restriction for examination purposes as indicated is proper.

13. Because these inventions are distinct for the reasons given above and the search required for Group IV is not required for Groups I, II, III, V, VI, and VII, restriction for examination purposes as indicated is proper.

14. Because these inventions are distinct for the reasons given above and the search required for Group V is not required for Groups I, II, III, IV, VI, and VII, restriction for examination purposes as indicated is proper.

15. Because these inventions are distinct for the reasons given above and the search required for Group VI is not required for Groups I, II, III, IV, V, and VII, restriction for examination purposes as indicated is proper.

16. Because these inventions are distinct for the reasons given above and the search required for Group VII is not required for Groups I, II, III, IV, V, and VI, restriction for examination purposes as indicated is proper.

Election/Restrictions

17. Applicant's election with traverse of Species I in the Paper dated 22 January 2004 is acknowledged. The traversal is on the ground(s) that Applicant believes that claims 3, 5, 12, 17, 18, 20, 25, 38, 39, 47, 60, 61, 65, 66, 67, 69, 70, 74, 75, 76, 78, 79, 81, and 82 are generic to all species. This is not found persuasive because as shown here in this restriction upon the elected

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species, the claims that applicant lists as generic are subject to a further restriction requirement since the examiner, as asserted before, feels that there are no claims that are generic to all species. Though the examiner thanks the applicant for providing an easy to read chart to show his election of Species I, there are still claims amongst the group claimed to be of species one that are distinct from one another.

The election of species requirement is still deemed proper and is therefore made FINAL.

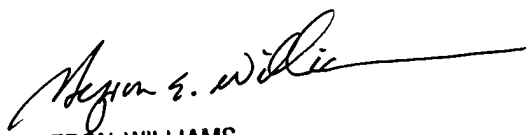
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney T. Frank whose telephone number is (571) 272-2193. The examiner can normally be reached on M-F 9am -5:30p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTF
March 1, 2004


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